

PCT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of: Barry Byrne et al.

§ Attorney Docket No.: 36689.250

Appl. No. 10/519,812

§ Group Art Unit: Unknown

Filed: December 28, 2004

§ Examiner: Unknown

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For: rAAV COMPOSITIONS AND METHODS FOR DELIVERY OF HUMAN FACTOR VII
POLYPEPTIDES AND TREATMENT OF HEMOPHILIA A

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the duty of disclosure under 37 CFR §1.56, and in accordance with the practice under 37 CFR §1.97 and §1.98, the Examiner's attention is directed to the documents listed on the enclosed modified Form PTO-1449. No inference should be made that the cited references are in fact material, are in fact prior art, or that no better art exists. The cited patents are listed in numerical order and are not in any order based on their pertinence.

Pursuant to 37 CFR 1.98 (a)(2)(i), copies of the U.S. patent documents listed on the enclosed modified Form PTO-1449 are not attached.

This Information Disclosure Statement is being filed within three months of the United States filing date or before the mailing date of a first Office Action on the merits. No certification or fee is required (37 CFR §1.97(b)).

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account 08-1394, order number 36689.250.

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Respectfully submitted,

Mark D. Moore, Ph.D.
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Date: 5/4/06
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H-607802

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 5/4/06.

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In place of PTO-449 Form	U. S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>					
SHEET	1	OF	2		
Attorney Docket Number 4300.014300 (36689.250)					

U. S. PATENT DOCUMENTS				
Examiner's Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		6,333,194 B1	12-25-2001	Levy et al.
		6,943,153 B1	09-13-2005	Manning Jr et al.
		2001/0034054 A1	10-25-2001	Dwarki et al.
		2001/0051611 A1	12-13-2001	Srivastava et al.
		2002/0132336 A1	09-19-2002	Dwarki et al.
		2002/0194630 A1	12-19-2002	Manning Jr et al.
		2003/0166284 A1	09-04-2003	Srivastava et al.

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Cite No.	Foreign Patent Document (Country Code – Number – Kind)	Publication Date MM-DD-YYYY	Patentee or Applicant of Cited Document	Translation Y/N
		EP 0844 004 A1	05-27-1998	Koken Company Limited Sumitomo Pharmaceuticals Company Limited	N
		WO 00/50584	08-31-2000	University of Iowa Research Foundation	N
		WO 00/54813 A2	09-21-2000	Manning et al.	N
		WO 02/24234 A2	03-28-2002	McGee et al.	N
		WO 2005/014775 A2	02-17-2005	University of Florida Research Foundation, Inc.	N
		WO 2005/014775 A3	02-17-2005	University of Florida Research Foundation, Inc.	N
		WO 2005/077333 A2	08-25-2005	University of Florida Research Foundation, Inc.	N
		WO 2005/077333 A3	08-25-2005	University of Florida Research Foundation, Inc.	N

NON-PATENT LITERATURE DOCUMENTS		
Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article, title of the item, date, page(s), volume-issue number(s), publisher, city/country where published
		ANWER et al., "Recent Progress in Polymeric Gene Delivery Systems," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 20(4):249-293, 2003.
		BROKX et al., "Peptide- and Polymer-Based Gene Delivery Vehicles," <i>Methods Mol. Med.</i> , 90:139-160, 2004.
		DAI et al., "Adenovirus-mediated Gene Transfer to Healing Tendon: Enhanced Efficiency Using a Gelatin Sponge," <i>J Orthopaedic Research</i> , 21(4):604-609, July 2003.
		FRAITES et al., "Correction of the Enzymatic and Functional Deficits in a Model of Pompe Disease Using Adeno-Associated Virus Vectors," <i>Molecular Therapy: J. of American Society of Gene Therapy</i> , 5(5):571-578, May 2002..
		FRAITES et al., "Gel-Based Delivery of Recombinant AAV Vectors to Adult Murine Diaphragm," <i>Molecular Therapy</i> , 7(5):S99-S100, May 2003.
		FRAITES et al., "Gene Replacement Therapy for Glycogen Storage Disease Type II with Recombinant Adeno-associated Virus Serotype 1 (AAV1) Vectors," <i>Circulation</i> , 106(19):II-127, November 2002.
		HAN et al., "Water-Soluble Lipopolymer for Gene Delivery," <i>Bioconjug. Chem.</i> , 12(3):337-345, 2001.
		International Search Report, Application Number PCT/US03/20746; dated November 14, 2005
		International Search Report and the Written Opinion of the International Searching Authority, International Application Number PCT/US2005/004146, dated February 10, 2006
		LANCIOTTI et al., "Targeting Adenoviral Vectors Using Heterofunctional Polyethylene Glycol FGF2 Conjugates," <i>Mol. Ther.</i> , 8(1):99-107, July 2003.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.



In place of
PTC-1449

U. S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

SHEET	2	OF	2	Attorney Docket Number	4300.014300 (36689.250)
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NON-PATENT LITERATURE DOCUMENTS

		LI <i>et al.</i> , "CNS Gene Transfer Mediated by a Novel Controlled Release System Based on DNA Complexes of Degradable Polycation PPE-EA: a Comparison with Polyethylenimine/DNA Complexes," <i>Gene Ther.</i> , 11(1):109-114, January 2004.
		LI <i>et al.</i> , "Controlled Gene Delivery System Based on Thermosensitive Biodegradable Hydrogel," <i>Pharmaceutical Research</i> , 20(6): 884-888, June 2003.
		MAH <i>et al.</i> , "A New Method for Recombinant Adeno-Associated Virus Vector Delivery to Murine Diaphragm," <i>Molecular Therapy: J. of American Society of Gene Therapy</i> ; 9(3):458-463, March 2004.
		MAH <i>et al.</i> , "Improved Method of Recombinant AAV2 Delivery for Systematic Targeted Gene Therapy," <i>Molecular Therapy</i> , 6(1):106-112, July 2002.
		OKINO <i>et al.</i> , "Novel Therapeutic Strategy for Prevention of Malignant Tumor Recurrence After Surgery: Local Delivery and Prolonged Release of Adenovirus Immobilized in Photocured, Tissue-Adhesive Gelatinous Matrix," <i>J. Biomed. Mater. Res.</i> , 66A(3):643-651, September 1, 2003.
		SIEMENS <i>et al.</i> , "Viral Delivery in a Gelatin Sponge Matrix Enhances Gene Expression and Antitumor Activity in a Murine Prostate Cancer Model," <i>J. Urology</i> , 161(4):61, May 1999.
		TRUONG <i>et al.</i> , "Delivery of DNA Vaccine Using Gelatin-DNA Nanospheres," <i>Proceedings of the 24th International Symposium on Controlled Release of Bioactive Material, SYMP.</i> 24:39-40, June 1997.
		Partial International Search Report, Application Number PCT/US2005/004141, dated November 3, 2005.
		YI <i>et al.</i> , "A Catatonic Lipid Emulsion/DNA Complex as a Physically Stable and Serum-Resistant Gene Delivery System," <i>Pharmaceutical Research</i> , 17(3):314-320, 2000.

Examiner Signature		Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.